

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION

REC'D 05 OCT 2004

REPORT PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 706707	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001494	International Filing Date (day/month/year) 12 November 2003	Priority Date (day/month/year) 15 November 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. <sup>7</sup> A61F 2/02		
Applicant CAREY TASCA PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 5 March 2004	Date of completion of the report 28 September 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer <i>S. Thomas</i> SUE THOMAS Telephone No. (02) 6283 2454

**I. Basis of the report**

1. With regard to the elements of the international application:\*
- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ Filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1-42	YES
	Claims	NO
Inventive step (IS)	Claims 1-42	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-42	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purpose of this report:

D1: WO 2002/078568 A1

D2: WO2001/006951 A1

D3: WO 2002/078552 A1

**NOVELTY (N) Claims 1-42**

The features of claims 1-42 are not found in any single cited document published before the earliest priority date of the claims and are considered to involve an inventive step of the prior art.

D1 discloses a treatment of a hernia (such as a uterovaginal prolapse) and, in particular, to a surgical implant for use in such treatment and to a surgical procedure.

The minimally invasive method of treating uterovaginal prolapse according to D1 comprises the steps of making a small incision in the vaginal wall, making a subcutaneous cut through the incision to provide a space between the upper and lower layers of the wall, and inserting a mesh through the incision, into the space defined by the cut. This is a different method than making an incision and lateral dissection through the arcus tendineus fascia pelvis and positioning the mesh directly onto exposed fascia that has been separated from the epithelium as disclosed in the claimed invention.

The surgical implant disclosed in D1 comprises a mesh consisting of strands and includes a plurality of major spaces and pores. The strands of the mesh may be formed by at least two filaments which may be interwoven/knitted, knotted or twisted to form pores of suitable dimensions. Therefore the junctions between the respective strands may include open interstices.

D1 does not disclose the use of an intra-vaginal splint located into the vagina after the vaginal epithelium is re-fixed over the mesh and fascia.

D2 discloses a corrective mesh for body tissues which comprises a main body provided with at least a pair of upper lateral fins substantially rectangular shaped with rounded vertexes. The method of positioning the mesh comprises the steps of making a small cut under the urethra, generating a suitable space, and placing the mesh inside above the pubis. D2 does not disclose laterally dissecting the arcus tendineus fascia pelvis, positioning mesh formed from junctions without open interstices onto exposed fascia, or the use of an intra-vaginal splint.

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of V**

D3 discloses a treatment of vaginal or vault prolapse and a device suitable for use in such treatment. The device comprises a strip made from a light mesh formed from an absorbable or non-absorbable thread with a drawstring threaded in and out of the mesh openings.

The method of treating vaginal prolapse according to D3 comprises attaching a strip of mesh between the pelvic floor and the vault, using the drawstring to reduce the length of the strip, thereby pulling the vault towards the pelvic floor. D3 does not disclose laterally dissecting the arcus tendineous fascia pelvie, positioning mesh formed from junctions without open interstices onto exposed fascia, or the use of an intra-vaginal splint.

**INVENTIVE STEP (IS) Claims 1-42**

Prior art documents D1-D3 do not disclose or teach towards a method for repairing a vaginal wall damaged by prolapsed pelvic organs which include the steps of mobilising the vaginal epithelium off underlying fascia by laterally dissecting the arcus tendineous fascia pelvie, positioning a mesh formed from junctions without open interstices onto the exposed fascia, re-fixing the vaginal epithelium over the mesh and fascia, and locating an intra-vaginal splint into the vagina. When the claimed invention is considered as a whole, it would not have been obvious to a person skilled in the art to combine these features in light of documents D1-D3. It is therefore considered the claimed invention involves an inventive step over these documents.